

Attorney Docket No. 12777.8US01

MERCHANT & GOULD P.C.

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: A METHOD FOR DETECTING MYCOBACTERIUM TUBERCULOSIS BY PCR AMPLIFICATION REP 13E12 REPEATED SEQUENCE

The specification of which

- a. ☒ is attached hereto
b. ☒ was filed on _____ as application serial no. _____ and was amended on _____ (if applicable) (in the case of a PCT-filed application) described and claimed in international no. _____ filed _____ and as amended on _____ (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

- a. ☐ no such applications have been filed.
b. ☒ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC § 119			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)
KOREA	10-2000-7984	19-FEBRUARY-2000	
ALL FOREIGN APPLICATION(S), IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

I hereby claim the benefit under Title 35, United States Code, § 120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

U.S. PROVISIONAL APPLICATION NUMBER	DATE OF FILING (Day, Month, Year)

I acknowledge the duty to disclose information that is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (reprinted below):

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby appoint the following attorney(ies) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Albrecht, John W.	Reg. No. 40,481
Ali, M. Jeffer	Reg. No. 46,359
Anderson, Gregg I.	Reg. No. 28,828
Batzli, Brian H.	Reg. No. 32,960
Beard, John L.	Reg. No. 27,612
Berns, John M.	Reg. No. 43,496
Black, Bruce E.	Reg. No. 41,622
Branch, John W.	Reg. No. 41,633
Bremer, Dennis C.	Reg. No. 40,528
Bruess, Steven C.	Reg. No. 34,130
Byrne, Linda M.	Reg. No. 32,404
Campbell, Keith	Reg. No. P-46,597
Carlson, Alan G.	Reg. No. 25,959
Caspers, Philip P.	Reg. No. 33,227
Chiapetta, James R.	Reg. No. 39,634
Clifford, John A.	Reg. No. 30,247
Coldren, Richard J.	Reg. No. 44,084
Daignault, Ronald A.	Reg. No. 25,968
Daley, Dennis R.	Reg. No. 34,994
Dalglish, Leslie E.	Reg. No. 40,579
Daulton, Julie R.	Reg. No. 36,414
DeVries Smith, Katherine M.	Reg. No. 42,157
DiPietro, Mark J.	Reg. No. 28,707
Edell, Robert T.	Reg. No. 20,187
Epp, Ryan, Sandra	Reg. No. 39,667
Glaner, Robert J.	Reg. No. 40,620
Goggin, Matthew J.	Reg. No. 44,125
Golla, Charles E.	Reg. No. 26,896
Gorman, Alan G.	Reg. No. 38,472
Gould, John D.	Reg. No. 18,223
Gregson, Richard	Reg. No. 41,804
Gresens, John J.	Reg. No. 33,112
Hamier, Samuel A.	Reg. No. 46,754
Hamire, Curtis B.	Reg. No. 29,165
Harrison, Kevin C.	Reg. No. P-46,759
Hertzberg, Brett A.	Reg. No. 42,660
Hillson, Randall A.	Reg. No. 31,838
Holzer, Jr., Richard J.	Reg. No. 42,668
Johnston, Scott W.	Reg. No. 39,721
Kadievitch, Natalie D.	Reg. No. 34,196
Karjeker, Shaukat	Reg. No. 34,049
Kastelic, Joseph M.	Reg. No. 37,160
Kettelberger, Denise	Reg. No. 33,924
Keys, Jeramie J.	Reg. No. 42,724
Knearl, Homer L.	Reg. No. 21,197
Kowalchyk, Alan W.	Reg. No. 31,535
Kowalchyk, Katherine M.	Reg. No. 36,848
Lacy, Paul E.	Reg. No. 38,946
Larson, James A.	Reg. No. 40,443

Leon, Andrew J.	Reg. No. 46,869
Leonard, Christopher J.	Reg. No. 41,940
Liepa, Mara E.	Reg. No. 40,066
Lindquist, Timothy A.	Reg. No. 40,701
Lycke, Lawrence E.	Reg. No. 38,540
Mayfield, Denise L.	Reg. No. 33,732
McDonald, Daniel W.	Reg. No. 32,044
McIntyre, Jr., William F.	Reg. No. 44,921
Mitchem, M. Todd	Reg. No. 40,731
Mueller, Douglas P.	Reg. No. 30,300
Nichols, A. Shane	Reg. No. 43,836
Pauly, Daniel M.	Reg. No. 40,123
Phillips, Bryan K.	Reg. No. P-46,990
Phillips, John B.	Reg. No. 37,206
Prendergast, Paul	Reg. No. 46,068
Pytel, Melissa J.	Reg. No. 41,512
Qualey, Terry	Reg. No. 25,148
Reich, John C.	Reg. No. 37,703
Reiland, Earl D.	Reg. No. 25,767
Samuels, Lisa A.	Reg. No. 43,080
Schmaltz, David G.	Reg. No. 39,828
Schuman, Mark D.	Reg. No. 31,197
Schumann, Michael D.	Reg. No. 30,422
Scull, Timothy B.	Reg. No. 42,137
Sebald, Gregory A.	Reg. No. 33,280
Skoog, Mark T.	Reg. No. 40,178
Spellman, Steven J.	Reg. No. 45,124
Stoll-DeBell, Kirstin L.	Reg. No. 43,164
Sumner, John P.	Reg. No. 29,114
Swenson, Erik G.	Reg. No. 45,147
Tellekson, David K.	Reg. No. 32,314
Trembath, Jon R.	Reg. No. 38,344
Tuchman, Ido	Reg. No. 45,924
Tunheim, Marcia A.	Reg. No. 42,189
Underhill, Albert L.	Reg. No. 27,403
Vandenburgh, J. Derek	Reg. No. 32,179
Wahl, John R.	Reg. No. 33,044
Weaver, Karrie G.	Reg. No. 43,245
Welter, Paul A.	Reg. No. 20,890
Whipps, Brian	Reg. No. 43,261
Whitaker, John E.	Reg. No. 42,222
Wickhem, J. Scot	Reg. No. 41,376
Williams, Douglas J.	Reg. No. 27,054
Withers, James D.	Reg. No. 40,376
Witt, Jonelle	Reg. No. 41,980
Wu, Tong	Reg. No. 43,361
Xu, Min S.	Reg. No. 39,536
Zeuli, Anthony R.	Reg. No. 45,255

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/ organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Merchant & Gould P.C. to the contrary.

Please direct all correspondence in this case to Merchant & Gould P.C. at the address indicated below:

Merchant & Gould P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903



I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2	Full Name Of Inventor	Family Name LEE	First Given Name Tao-Yoon	Second Given Name
0	Residence & Citizenship	City Daegu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
1	Mailing Address	Address Main Bldg, STE 512, Yeungnam University Col. Med., 317-1, Daemyung-dong, Nam-gu		City Daegu-shi State & Zip Code/Country KOREA
Signature of Inventor 201:			Date: January 22, 2001	
2	Full Name Of Inventor	Family Name KIM	First Given Name Sung-Kwang	Second Given Name
0	Residence & Citizenship	City Daegu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
2	Mailing Address	Address Main Bldg, STE 512, Yeungnam University Col. Med., 317-1, Daemyung-dong, Nam-gu		City Daegu-shi State & Zip Code/Country KOREA
Signature of Inventor 202:			Date: January 22, 2001	
2	Full Name Of Inventor	Family Name LEE	First Given Name Jong-Seok	Second Given Name
0	Residence & Citizenship	City Daegu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
3	Mailing Address	Address Main Bldg, STE 512, Yeungnam University Col. Med., 317-1, Daemyung-dong, Nam-gu		City Daegu-shi State & Zip Code/Country KOREA
Signature of Inventor 203:			Date: JANUARY 22, 2001	
2	Full Name Of Inventor	Family Name LEE	First Given Name Jai-Youl	Second Given Name
0	Residence & Citizenship	City Daegu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
4	Mailing Address	Address 1370, Sankok-dong, Book-gu		City Daegu-shi State & Zip Code/Country KOREA
Signature of Inventor 204:			Date: January 22, 2001	

SMALL BUSINESS**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 C.F.R. 1.9(f)) - SMALL BUSINESS CONCERN**

I hereby declare that I am

- a) ☐ the owner of the small business concern identified below:
 b) ☐ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: BIOGENIA CO., LTD.
 ADDRESS OF CONCERN: Owner Venture Bldg. Ste 409
 1661, Bongchun-dong, Kwanack-gu
 Seoul, KOREA

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. 121.801-805, and reproduced in 37 C.F.R. 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled A METHOD FOR DETECTING MYCOBACTERIUM TUBERCULOSIS BY PCR AMPLIFICATION REP 13E12 REPEATED SEQUENCE by inventor(s) LEE, TAE-YOON; KIM, SUNG-KWANG; LEE, JONG-SEOK; LEE, JAI-YOUL described in

- a) ☐ the specification filed herewith.
 b) ☐ provisional application serial no. _____, filed _____.
 c) ☒ non-provisional application serial no. _____, filed _____.
 d) ☐ patent no. _____, issued _____.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 C.F.R. 1.9(c) or by any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).

NAME: _____

ADDRESS: _____

a) ☐ INDIVIDUALb) ☐ SMALL BUSINESS CONCERNc) ☐ NONPROFIT ORGANIZATION

NAME: _____

ADDRESS: _____

a) ☐ INDIVIDUALb) ☐ SMALL BUSINESS CONCERNc) ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.27(g)(2))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.

NAME: _____

TITLE: _____

ADDRESS: _____

SIGNATURE: _____

Date: _____

January 22, 2001



23552

PATENT TRADEMARK OFFICE

M&G: 12777.BUS01

INDEPENDENT INVENTOR(S)**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 C.F.R. 1.9(f)) - INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled A METHOD FOR DETECTING MYCOBACTERIUM TUBERCULOSIS BY PCR AMPLIFICATION REP 13E12 REPEATED SEQUENCE described in

- a) ☐ the specification filed herewith.
 b) ☐ provisional application serial no. _____, filed _____
 c) ☒ non-provisional application serial no. _____, filed _____
 d) ☐ patent no. _____, issued _____

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 C.F.R. 1.9(c) if that person has made the invention, or to any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- a) ☐ no such person, concern, or organization
 b) ☒ persons, concerns or organizations listed below*

NAME BIOGENIA CO., LTD.,
 ADDRESS Owner Venture Bldg. Ste 409, 1661, Bongchun-dong, Kwanack-gu, Seoul, KOREA
 a) ☐ INDIVIDUAL b) ☒ SMALL BUSINESS CONCERN c) ☐ NONPROFIT ORGANIZATION

NAME LEE, Tae-Yoon
 ADDRESS Main Bldg, STE 512, Yeungnam University Col. Med., 317-1, Daemyung-dong, Nam-gu, Daejeon-shi, KOREA
 a) ☒ INDIVIDUAL b) ☐ SMALL BUSINESS CONCERN c) ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.27(g)(2))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.

NAME OF INVENTOR	KIM, Sung-Kwang	LEE, Jong-Seok	LEE, Jai-Youl
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
Signature of Inventor	Signature of Inventor	Signature of Inventor	Signature of Inventor
Date	Date	Date	Date

김성광

이종석

이재율

January 22, 2001

January 22, 2001

January 22, 2001

January 22, 2001

January 22, 2001

January 22, 2001



23552

PATENT TRADEMARK OFFICE

M&G: 12777.81US01

INDEPENDENT INVENTOR(S)**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 C.F.R. 1.9(f)) - INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled A METHOD FOR DETECTING MYCOBACTERIUM TUBERCULOSIS BY PCR AMPLIFICATION REP 13E12 REPEATED SEQUENCE described in

- a) ☐ the specification filed herewith.
 b) ☐ provisional application serial no. _____, filed _____.
 c) ☒ non-provisional application serial no. _____, filed _____.
 d) ☐ patent no. _____, issued _____.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 C.F.R. 1.9(c) if that person has made the invention, or to any concern which would not qualify as a small business concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- a) ☐ no such person, concern, or organization
 b) ☒ persons, concerns or organizations listed below*

NAME BIOGENIA CO., LTD.,ADDRESS Owner Venture Bldg. Ste 409, 1661, Bongchun-dong, Kwanack-gu, Seoul, KOREAa) ☐ INDIVIDUAL b) ☒ SMALL BUSINESS CONCERN c) ☐ NONPROFIT ORGANIZATION

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.

LEE, Tae-Yoon

NAME OF INVENTOR NAME OF INVENTOR NAME OF INVENTOR NAME OF INVENTOR

Signature of Inventor Signature of Inventor Signature of Inventor Signature of Inventor

Date Date Date Date

**23552**

PATENT TRADEMARK OFFICE